

**REMARKS**

Upon entry of the Amendment, claims 1-39 are all the claims pending in the application.

Claims 35 to 39 are new. Claims 8-15, 24-27, and 29-34 are withdrawn from consideration.

Claims 1, 3-5, 8, 11-13, 16-21, 24-25, and 28-33 have been amended.

**I. Claim Objections**

Claim 28 has been objected to allegedly because of the informality that claim 28 depends from non-elected claim 8.

Claim 28 has been amended so that it does not depend from claim 8.

**II. Claims Rejections 35 U.S.C. § 112**

Claims 1-7, 16-23 and 28 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

The Examiner asserts that claim 1 is unclear as it recites the phrase fluoroalkylene block.

The specification describes that “a pendant group containing a fluoroalkylene block refers to a pendant group comprising a fluoroalkylene as a component unit thereof. On the other hand, a fluoroalkylene refers to an alkylene group, part of all of whose hydrogen atoms are replaced with fluorine atoms.” *See* page 41, lines 4 to 9. In light of this description in the specification, a person skilled in the art would understand the metes and bounds of claim 1.

Further, U.S. Patent No. 6,464,848 and U.S. Patent No. 6,289,587 also contain a claim reciting the phrase “a polymer in which a pendant group containing at least a fluoroalkylene block is attached to a non-fluorinated vinyl polymer.” In this regard, Applicants respectfully

submit that a person skilled in the art would understand the metes and bounds of the claim 1 in the present application.

With respect to claim 16, the Examiner asserts that the language “the uppermost surface,” “essentially comprising,” “many grooves,” and “built” is unclear. Claim 16 has been amended so that it does not recite “the uppermost surface,” “many grooves” or “built.” Further, Applicants respectfully submit that the phrase “essentially comprising” is clear.

With respect to claim 17, the Examiner asserts that the phrase “a surface roughness within a range of 0.0001 or more and 1 or less fold of said average thickness of the permeation-limiting layer” is unclear. Claim 17 has been amended to improve its clarity.

As to the other issues raised by the Examiner, Applicants respectfully submit that they have been addressed in the amended claims as set forth above.

### **III. Claims Rejections – 35 U.S.C. § 103**

(A) Claims 1-7 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0 969 282 A2 (“EP ‘282”) in view of U.S. Patent No. 5,696,314 to McCaffrey *et al.* (“McCaffrey ‘314”) and U.S. Patent No. 5,200,051 to Cozzette *et al.* (“Cozzette ‘051”).

Claim 1 recites the presence of an adhesion layer comprising a silane-containing compound formed over an immobilized enzyme layer and a permeation-limiting layer formed on the adhesion layer.

EP ‘282 teaches an enzyme electrode comprising: (1) an electrode formed on an insulating substrate; (2) a binding layer (adhesion layer) mainly consisting of a silane coupling agent; (3) an immobilized enzyme layer formed on the binding layer; and (4) a permeation-

limiting layer comprising a fluorine-containing polymer having a structure where a pendant group containing at least a fluoroalkylene block is attached to an unfluorinated vinyl-based polymer.

EP '282 also teaches the use of the binding layer being disposed between the electrode and the immobilized enzyme layer, rather than between an immobilized enzyme layer and a permeation-limiting layer. For example, as to the binding layer being formed to cover the insulating substrate and the electrode, as shown in Figure 1 thereof, EP '282 teaches that the binding layer may improve adhesiveness (binding strength) of the immobilized enzyme layer to the insulating substrate and the electrode. The binding layer is also effective in improving wettability of the surface of the insulating substrate and thickness uniformity during forming the immobilized enzyme layer in which an enzyme is immobilized. The binding layer also exhibits selective permeation to ascorbic acid, uric acid, and acetaminophen which may interface with a reaction of hydrogen peroxide on the electrode.

McCaffrey '314 teaches a multilayer enzyme electrode in which an enzyme/polymer layer is employed to increase the time period over which the blood/aqueous slope sensor is constant. In this regard, McCaffrey '314 teaches that the enzyme/polymer layer is disposed in an area above the area defined by the immobilized enzyme layer. It follows that the adhesive layer thereof is used to promote adhesion between the enzyme/polymer layer and the immobilized enzyme layer or to isolate the enzyme/polymer layer from the immobilized enzyme layer. Furthermore, the adhesive layer is used to promote adhesion between a dielectric layer and a microporous layer. *See* col. 7, lines 46-59 and col. 9, lines, 20-27.

Cozette '051 teaches a biosensor containing multiple layers, in which a silane layer underlying a biolayer (immobilized enzyme layer) is used to improve adhesiveness (binding strength) of the immobilized enzyme layer to an electrode. Further, Cozette '051 teaches a process for forming the silane layer on the electrode and an insulating film (i.e., silicon oxide) using a silane coupling agent, in which process a liquid mixture of silane compound with a solvent is applied onto the surface of the electrode and the insulating film. The surface of the electrode and the insulating film lacks "detailed" rough topography that would promote adhesion between the component layers. The silane layer formed with silane coupling agent is employed to promote adhesion to the underlying surface that lacks "detailed" rough topography.

Cozette '051 also teaches that the silane layer covering the electrode is used as a semi-permeable solid which promotes adhesion of the immobilized enzyme layer onto the electrode and is able to act as a small-molecule-selective membrane fit to selectively perm hydrogen peroxide produced in the immobilized enzyme layer.

In contrast, EP '282 discloses that the polymer is used for a permeation-limiting layer and has a non-fluorinated vinyl polymer structure as a principal chain, which is adhesive to another organic polymer layer such as an immobilized enzyme layer.

Accordingly, EP '282 fails to suggest a modification that, in place of the binding layer between the immobilized enzyme layer and the electrode or substrate, an adhesion layer comprising a silane-containing compound is formed as an intervening layer between the immobilized enzyme layer and the permeation-limiting layer, which is made of the polymer being highly adhesive to the immobilized enzyme layer.

Similarly, McCaffrey '314 and Cozzette '051 both fail to suggest the desirability that would have caused a structure in which the adhesion layer comprising a silane-containing compound is formed as an underlying layer of the permeation-limiting layer itself having an excellent adhesion activity to another organic polymer layer such as an immobilized enzyme layer.

As the permeation-limiting layer of EP '282 is made of the polymer being highly adhesive to the immobilized enzyme layer, there is no motivation for providing any further layer to promote adhesion between the permeation-limiting layer and the immobilized enzyme layer of EP '282.

In this view, EP '282, McCaffrey '314 and Cozzette '051 fail to suggest any motivation to use an adhesion layer between the permeation-limiting layer and the immobilized enzyme layer of EP '282.

Additionally, claims 2-7 and 28 depend directly or indirectly from claim 1. In this regard, claims 2-7 and 28 are non-obvious for at least the same reasons as claim 1.

(B) Claims 16, 18-23 and 28 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP '282 in view of U.S. Patent No. 6,461,861 to Schillig *et al.* ("Schillig '861").

Claim 16 presently recites that a plurality of grooves with depth selected in a range of 0.1 to 100 nm, which is due to variation of the thickness of said permeation-limiting layer, are present on the surface of a permeation-limiting layer.

Schillig '861 teaches a microbial membrane reactor including a membrane sandwiched between opposed surfaces of first and second structural elements. Schillig '861 teaches that the inner surface of the second element that abuts the membrane is provided with one or more flow channels for flow of the fluid over the surface of the membrane.

Schillig '861 teaches a structure in which one or more flow channels are formed on the inner surface of the second element that abuts the membrane. Schillig '861 fails to suggest a local structure in which the layer having grooves on the outer surface thereof is formed on the immobilized enzyme layer, where the inner surface of the second element that abuts the immobilized enzyme layer has no flow channels.

In this regard, EP '282 and Schillig '861 fail to provide any suggestion about a local structure that the outer surface (top surface) of the permeation-limiting layer formed on the adhesion layer has grooves, where the inner surface (interface) of the permeation-limiting layer with the adhesion layer has no grooves. In this regard, the grooves of Schillig '841 formed in the outer surface (top surface) are by no means used as flow channels for flow of the fluid over the surface of the immobilized enzyme layer.

(C) Claim 17 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP '282 in view of Schillig '861, and further in view of Cozzette '051

For the same reasons provided above, EP '282, Schillig '861, and Cozzette '051 fail to suggest the use of an adhesion layer between the permeation-limiting layer and the immobilized enzyme layer of EP '282.

#### **IV. Double Patenting**

The Office Action includes four rejections on the grounds of non-statutory obviousness-type double patenting, as follows:

Claims 1-7 and 28 have been rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-53 of U.S. Patent No. 6,280,587 to Matsumoto ("Matsumoto '587") in view of McCaffrey '314 and Cozzette '051;

Claims 16, 18-23 and 28 have been rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-53 of Matsumoto '587 in view of Schillig '861;

Claims 1-7 and 28 have been rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-62 of U.S. Patent No. 6,464,848 to Matsumoto ("Matsumoto '848") in view of Matsumoto '587 and McCaffrey '314 and Cozzette '051; and

Claims 16, 18-23 and 28 have been rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-62 of Matsumoto '848 in view of Matsumoto '587 and Schillig '861.

Accordingly, each of the rejections above grounded on non-statutory obviousness type double patenting cite Matsumoto '587. Matsumoto '587 is the U.S. counterpart of EP '282. For the same reasons as the § 103 rejections, Applicants respectfully submit that claims 1-7, 16, 18-23, and 28 are patentable over the cited references.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111  
Appln. No.: 10/718,729

Docket No: Q78586

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


Respectfully submitted,

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

  
Ken Sakurabayashi  
Registration No. 58,490

Date: March 26, 2007